DEC 21 2000

# Multi Media Dental Systems, Inc.

## 510(K) Summary

K002425

Submitter Information:

MultiMedia Dental Systems, Inc.
1302 Macy Dr.
Roswell, GA 30076
770-998-7386
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email: scottm@multimediadental.org

Name of Device:

Trade name: Mediadent HDX Digital Xray Sensor
Common name: intraoral digital xray sensor
Classification name: Unit, Xray, ~~Intraoral~~ (per 21 CFR section ~~872.810~~) 892.1800

Substantially Equivalent Devices:

Computed Oral Radiology System K933455
Trophy Radiologie RVG Portable Radiovisiography K950532

Device Description:

Digital dental intraoral Xray sensor

Intended Use:

Taking dental intraoral diagnostic Xrays

Technological Characteristics compared to predicate devices:

The Mediadent HDX Digital Xray Sensor is virtually identical to the Trophy Radiologie RVG Portable Radiovisiography sensor in size, manufacture and materials. The only difference between it and the Computed Oral Radiology System is the type of sensor employed. It uses a CMOS sensor while the Mediadent HDX uses a CCD sensor. A minor design difference. All three are used in exactly the same manner and circumstances. All three use the same barrier protection for infection control.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 21 2000

Scott McLaughlin
President
Multi Media Dental Systems, Inc.
1302 Macy Dr.
Roswell, GA 30076

Re: K002425
Mediadent HDX Digital Xray Sensor
Dated: October 3, 2000
Received: October 4, 2000
Regulatory class: II
21 CFR 892.1800/Procode: 90 MUH

Dear Mr. McLaughlin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

# Multi Media Dental Systems, Inc.

## Indication for Use



510(K) Number **K002425**
Device Name **Mediadent HDX Digital Xray Sensor**

The Mediadent Digital Xray Sensor is designed to replace standard intraoral Xray film used in diagnosis ~~in dental~~ offices.

The Mediadent Digital Xray Sensor is covered with a sterile disposable sheath and placed in the oral cavity opposite the tooth the dentist wishes to Xray. The dental Xray tube (not part of this product) is pointed at the sensor and activated.

The Xray energy is detected by the sensor and transmitted as data to the computer it is ~~connected to~~. ~~The software~~ interprets the image as a gray scale image and displays it on the computer monitor for diagnosis.

(Please do not write below this line – Continure on another page if needed)

Concurrence of DCRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109 (Optional Format 1-2-96

David A. Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K002425